<u>REMARKS</u>

Applicant respectfully requests consideration of this application. The foregoing

amendments and the following arguments are provided to impart precision to the claims,

by more particularly pointing out the invention, rather than to avoid prior art.

Office Action Rejections Summary

Claims 1, 5 – 6, 8, 24, and 27 - 32 have been rejected under 35 U.S.C. § 102(e)

as being anticipated by Duffy, U.S. Patent No. 6,048,332 (hereinafter "Duffy"). Claims 2,

3, 10, and 11 have been rejected under 35 U.S.C. §103(a) as being unpatentable over

Duffy.

Status of Claims

Claims 1 - 6, 8, 10, 11, 24, and 27 - 32 remain pending in this application.

Claims 1, 24, 27, and 30 have been amended. The amendments are supported by the

specification and no new matter has been added. Claims 7, 9, 12 – 23 and 25 – 26 have

been canceled. No claims have been added.

35 U.S.C. § 102 (e) Rejections

Claims 1, 5 – 6, 8, 24, and 27 - 32 have been rejected under 35 U.S.C. § 102(e)

as being anticipated by Duffy. Applicant respectfully submits that claims 1, 5 – 6, 8, 24,

and 27 – 32 are patentable over Duffy.

Amended independent claim 1 provides:

A method comprising:

injuring a vessel region; and

delivering an arteriogenic factor to said vessel region in a medically effective manner to structurally enlarge an existing blood

vessel. (emphasis added)

Amended independent claim 24 provides:

A method of structurally enlarging an existing blood vessel, said method comprising:

injuring said existing blood vessel; and advancing a distal portion of a catheter to said existing blood vessel; and delivering an arteriogenic factor in a medically effective manner to said existing blood vessel via said catheter. (emphasis added)

Amended independent claim 27 provides:

An apparatus comprising:

an elongated catheter body; and

a distal portion of said elongated catheter body having a puncturing element, said distal portion configured to induce injury and deliver an arteriogenic factor to a vessel region in a medically effective manner to structurally enlarge an existing blood vessel. (emphasis added)

Duffy discloses a balloon catheter for delivering a therapeutic agent into a body lumen. The balloon wall includes concavities. Duffy also discloses:

The distance provided between the aperture 32 and the interior surface 44 of the body lumen 42 defines a space by which the aperture 32 is removed from the tissue wall. By increasing the distance between the aperture 32 through which the fluid vehicle exits the balloon 20 and the interior surface 44 of the body lumen 42 that the fluid vehicle strikes, the concavity 30 serves to reduce the velocity of this fluid stream and thus to reduce the physiologically detrimental effects of this contact. The systems and methods described herein can thereby diminish the damage caused by the jetting effects of the fluid striking the interior surface 44 of the body lumen 42 at excessive velocities. The concavity 30 further provides a site for collection of a volume of fluid vehicle bearing the therapeutic agent, thereby increasing the surface area over which this fluid contacts the interior surface 44 of the body lumen 42.

(emphasis added) (Duffy, col. 9, lines 20 – 36, and FIG. 3)

As such, nothing in Duffy discloses injuring or causing the injury of the body lumen. In fact, <u>Duffy attempts to avoid causing injury to the body lumen</u>, and in particular, the site of the therapeutic agent delivered by the balloon catheter.

In contrast, amended independent claim 1 includes the limitation of "injuring a vessel region," amended independent claim 24 includes the limitation of "injuring said existing blood vessel," and amended independent claim 27 includes the limitation of "a

Appln. No.: 09/749,144 Filing Date: 12/27/2000 distal portion of said elongated catheter body having a puncturing element, said distal portion configured to induce injury." Therefore, Applicant respectfully submits that claims 1, 24, and 27 are patentable over Duffy under 35 U.S.C. § 102(e).

Claims 5-6 and 8 depend either directly or indirectly from independent claim 1, and claims 28-32 depend either directly or indirectly from independent claim 27. As such, claims 5-6, 8, and 28-32 are also patentable over Duffy under 35 U.S.C. § 102(e).

## 35 U.S.C. § 103 (a) Rejections

Claims 2, 3, 10, and 11 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Duffy. Claims 2, 3, 10, and 11 depend from independent claim 1, and thus include the limitation "injuring a vessel region." As discussed above, nothing in Duffy discloses this limitation. Applicant respectfully submits that it would not be obvious in Duffy to injure a body vessel because <u>Duffy, in fact, teaches away from injuring the body vessel</u>. Duffy discloses that prior art PTA methods have problems of causing injury to vessel walls (e.g., see col. 2, lines 6 – 14, 43 – 48, col. 3, lines 36 – 42, and col. 4, lines 4 – 9). Applicant reiterates that Duffy also discloses that "The systems and methods described herein can thereby diminish the damage caused by the jetting effects of the fluid striking the interior surface 44 of the body lumen 42 at excessive velocities." As such, Applicant respectfully submits that claim 1 is patentable over Duffy under 35 U.S.C. §103(a). Accordingly, dependent claims 2, 3, 10, and 11 are also patentable over Duffy under 35 U.S.C. §103(a).

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## Conclusion

In conclusion, Applicant respectfully submits that in view of the amendments and arguments set forth herein, the applicable rejections have been overcome. If the allowance of these claims could be facilitated by a telephone conference, the Examiner is invited to contact Suk Lee at (408) 720-8300. If there are any additional charges, please charge our Deposit Account No. 02–2666.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP

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Suk S. Lee

Attorney for Applicant Reg. No. 47,745

12400 Wilshire Blvd. Seventh Floor Los Angeles, CA 90025-1030 (408) 720-8300